REMARKS/ARGUMENTS

Claims 1, 2, 5-6, 9, 14, and 19 are amended by this response. Claims 4, 7-8, 13, and 18 are canceled. Claims 20-25 are added. Accordingly, claims 1-3, 5-6, 9-12, 14-17, and 19-25 remain pending.

Certain portions of the specification have been revised in the manner recommended by the Examiner in the latest office action, in order to correct typographical errors. In addition, certain claims and other portions of the specification have been revised to change the term "trail" to "trial". No new matter is added by any of these amendments.

Embodiments in accordance with the present invention relate to systems and methods allowing the simulation of clinical trials. In particular, embodiments in accordance with the present invention are configured to receive clinical trial protocol information in the form of a plurality of independent schedules, such as dosing schedules and observation schedules. Source code is then generated and compiled to produce a state machine corresponding to each schedule. (See ¶[11-12]) These state machines are then executable according to a time-ordered queue. (See ¶[61-64]) In order to emphasize these elements, pending independent claims 1, 9, 14, and 19 have now been amended.

In the latest office action, the Examiner rejected the pending claims as obvious based upon U.S. patent no. 6,108,635 to Herren et al. ("the Herren Patent"), in combination with a multitude of other references. These claim rejections are traversed as follows.

The Herren patent describes a system comprising a plurality of modules designed to support the development of medical treatments. One such module, the "Clinical Trials Explorer", calls for the user to manually enter information regarding a "regimen" for treatment or intervention. (Col. 29, lines 55-56; col. 30, lines 4-6; and Fig. 12b, col. 30, lines 64-64). However, as explicitly acknowledged by the Examiner, the Herren Patent fails to teach a trial protocol for clinical trial simulation, and in particular fails to teach a clinical trial protocol comprising a plurality of schedules.

In an effort to provide this absent teaching, the Examiner has combined the Herren Patent with U.S. Patent No. 6,735,523 to Lin et al. ("the Lin Patent"). As a threshold matter, the Examiner is reminded that in order to establish a prima facie case of obviousness, "the prior art

reference (or references when combined) must teach or suggest all the claim limitations." MPEP 2142.

Here, the Lin Patent relates to methods simulating performance of differential global positioning system (GPS) devices. Such GPS systems allow for the rapid and precise location of an entity on the earth's surface, based upon reference to an array of orbiting satellites.

In relying upon the Lin Patent to reject the pending claims, the Examiner relied exclusively upon the following (brief) passage:

> An estimator 216 calculates the rover position and velocity. The position and velocity information and the simulated raw data are formatted by a data formatting 219 along with the ephemeris data according to a specific protocol. (Col. 15, lines 58-60)

This excerpt describes only the following general concept: formatting raw data according to a specific protocol. However, this use of the term "protocol" by the Lin Patent, bears no relation to the "clinical trial protocol" of the instant application. Neither the above-cited passage, nor any other portion of the Lin Patent, teaches or suggests receiving a drug development clinical trial protocol comprising a plurality of schedules, and then generating source code corresponding to a plurality of state machines from the trial protocol.

In further acknowledgement of the failure of the art relied upon to teach the claimed invention, the Examiner has combined the Herren and Lin Patents with U.S. Patent No. 5,808,918 to Fink et al. ("the Fink Patent"). Like the Lin Patent, however, the Fink Patent teaches only a general proposition: a schedule for administering medication is one parameter of a clinical trial. The Fink Patent says nothing to teach, or even to suggest, a method or system according to the present invention wherein a clinical trial protocol comprising a plurality of schedules is received, and source code is generated therefrom corresponding to a plurality of state machines.

The Examiner is further reminded that in order to establish a prima facie case of obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." (MPEP 2143). Any motivation to combine reference teachings must be found in the prior art, and not be based upon applicant's own disclosure:

> The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (Emphasis added; MPEP 2142).

Here, the complete lack of any nexus between the subject matter of the Herren and Lin Patents unmistakably reveals the improper use of hindsight.

Specifically, the Herren Patent contains little or no discussion of the data formatting issues raised (however briefly) by the above-cited passage from the Lin Patent. In fact, the Herren Patent describes a comprehensive system comprising four modules (the "Target Discovery Explorer", "Clinical Trials Explorer", "Parmacoeconomic Explorer", and "Disease Progression Explorer") specifically configured to share a common "Data/Information Source" and "Results Database" featuring data with the same format. (See Figure 2). Any inspiration to combine the Lin Patent with the Herren Patent can thus realistically only have originated from the instant application - an impermissible exercise in hindsight. On this ground alone, continued rejection of the pending claims is improper, and the claim rejections should be withdrawn.

Moreover, an additional and entirely separate ground for overcoming the Examiner's instant obviousness rejection is the widely disparate subject matter of the Lin Patent and the instant application. Specifically, it is well established that a reference relied upon to establish obviousness must lie either in the same field of endeavor as the application, or be reasonably pertinent thereto:

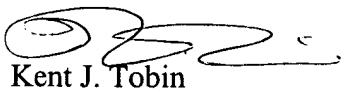
> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. MPEP 2141.01(a), citing In re Clay, 966 F.2d 656, 659 (Fed.Cir. 1992)

Here, it cannot reasonably be asserted that the Lin Patent is analogous art to the instant application. While both ostensibly relate to the simulation of complex systems, a reference describing simulation of differential global positioning systems would hardly have commended itself to the attention of an inventor grappling with problems of simulating behavior of a pharmaceutical entity in a clinical trial. Accordingly, there can be no question that the Lin Patent

lies far outside the realm of the instant application, and that continued rejection of the pending claims is improper for this reason as well.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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